



Employers allowed to coordinate retiree benefits with Medicare

Employers were allowed to continue to reduce their health insurance expenses for retired workers once they turn 65 and qualify for Medicare. The AARP made it as far as the Supreme Court, but at the end of the day, the policy was allowed to stand as it would mean employers would have dropped benefits altogether.

For more information on the Supreme Court, go to: www.supremecourtus.gov

For more information on MSP compliance in regards to Conditional Payments and Medicare Set Asides, please contact Louis Porrazzo, Esq. at lporrazzo@cpscmsa.com.

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Medicare Off-Label Coverage of FDA Approved Drugs

There has been a lot of interest in determining whether Medicare Set-Asides (MSA) need to include medications used for “off-label” uses. In reality, the Medicare Part D Prescription Plan often does not cover these off-label uses, which would make their inclusion into MSA’s unnecessary.

While CMS has not formally issued their opinion on this subject, it should be noted that Medicare references “the use of drugs for an indication, dosage form, dose regimen, population, or other parameter not included as an indication on the drug’s label as approved by the FDA.” Medicare noted that coverage of off-label FDA approved drugs was determined by taking into consideration the major drug compendia, authoritative medical literature and/or generally accepted medical practice in the community, and whether or not the FDA had specified such use as non-approved. (Medicare Local Coverage Determination (LCD) L13121)

FDA approved drugs used for indications other than those specified on the FDA approved labeling will be covered if the use is listed as an off-label use in the USPDI (United States Pharmacopoeia Dispensing Information).

FDA approved drugs used for indications other than those specified on the FDA approved labeling may be covered if:

- a) The use is supported (at a possibly effective level or higher) in one or more citations in the American Hospital Formulary Service Drug Information (AHFS) or the American Medical Association Drug Evaluations, AND the use is not listed as “not indicated”.
- b) A decision to support the use has been made by one of the above compendia and is forthcoming, with findings based upon reports in one of the following peer reviewed medical journals: American Journal of Medicine, Annals of Internal Medicine, Journal of the American Medical Association, Journal of clinical Oncology, Blood, Journal of the National Cancer Institute, New England Journal of Medicine, British Journal of Cancer, British Journal of Hematology, British Medical Journal, Cancer, Drugs, European Journal of Cancer, Lancet, or Leukemia. Peer reviewed medical literature does not include in-house publications of pharmaceutical manufacturing companies or abstracts.

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c) It is determined by the contractor to be “medically accepted generally as safe and effective for the particular use” (MCM 2049)

A drug is not covered if a use is:

- a) not indicated by CMS or the FDA
- b) not indicated in at least one of the two major compendia mentioned
- c) not safe and effective, based on peer reviewed medical literature

Investigational use of newly approved or established drugs is not covered by Medicare.

Off-label uses of anti-cancer chemotherapeutic drugs are covered for a medically accepted indication as defined in CMS Publication 100-2, 15, ss 50.4-50.4.4.1, 100-4, 18-ss10.2.

In developing allocations for prescription drugs in a MSA, it currently appears that unless an off-label use of a FDA approved medication is either listed in the major drug compendia, supported in specific peer-reviewed medical journals, or determined by the contractor to be medically accepted as safe and effective, the argument could be made that it does not need to be included in the allocations as it would not be expected to be a Medicare covered benefit. This can have a major impact on the total amounts that need to be allocated for prescription drugs in Medicare Set-Asides.

Governmental Opposition Swells Against Implementation of the 6th Edition of the AMA Guides

Attorney Jon Gelman, a workers compensation attorney in New Jersey, reports that “State governments throughout the United States are now delaying implementation of the 6th Edition of the AMA guides as a standard to determine permanent disability. The governmental officials are heeding warnings that the guides do not carry out the legislative intent of the workers’ compensation acts which is to provide a remedial social insurance benefit to injured workers.”

For more information, go to:

<http://workers-compensation.blogspot.com/2008/03/governmental-opposition-swells-against.html>

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